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EXAMINER	
NGUYEN, HUONG Q	
ART UNIT	PAPER NUMBER
3736	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/561,572	FADEM, KALFORD C.	
	Examiner	Art Unit	
	HUONG NGUYEN	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25 and 28-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25 and 28-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 April 2011* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the amendment filed 4/20/2011. Claims 1, 23, and 33 are amended. Claim 27 is cancelled. The amendment to the specification and drawings are acknowledged, rendering the previous drawing objections and §112 rejections moot. **Claims 1-25 and 28-33** remain pending and under prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. **Claims 1-3, 7, 11, and 13-22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Finkenzeller et al (US Pat No. 5954667) in view of John et al (US Pub No. 20010049480), further in view of Levendowski et al (US Pub No. 20020029005).

4. In regards to **Claim 1**, Finkenzeller et al disclose a screening device, comprising:

a frame 10 shaped to be engageable to a head between a reference location, at least one ear, and a signal detection location, best seen in Figure 1-2;

a reference active electrode 22 attached to the frame at the reference location, wherein the reference active electrode includes a local amplifier 40 co-located with the reference active electrode such that the local amplifier co-located with the reference active electrode is also attached relative to the frame, wherein the local amplifier co-

located with the reference active electrode is operable to amplify signals sensed by the reference active electrode, best seen in Figure 1-2;

a signal active electrode 21 attached to the frame at the signal detection location, wherein the signal active electrode includes a local amplifier 40 co-located with the signal active electrode such that the local amplifier co-located with the signal active electrode is also attached relative to the frame, wherein the local amplifier co-located with the signal active electrode is operable to amplify signals sensed by the signal active electrode, best seen in Figure 1-2;

an auditory signal producer 30 positionable by the frame over the ear; and

an auditory evoked response (AER) data processor 1 operably configured to initiate an auditory signal from the auditory signal producer and to perform a signal processing operation on an AER signal sensed across the reference and signal electrodes and amplified by the local amplifier co-located with the reference active electrode and the local amplifier co-located with the signal active electrode, best seen in Figure 1-2 (Col.3: 55-65).

5. However, Finkenzeller et al do not disclose the amplifier as an integral part of the reference active electrode or the signal active electrode, each with its own amplifier. Levendowski et al disclose an analogous electrode assembly also used to detect brain signals comprising a pre amplifier 174 integrated with each electrode assembly to advantageously take the place of a second stage differential amplification of the acquired signals, therefore simplifying the device, best seen in Figure 12 (¶0018, 0064, 0067). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Finkenzeller et al such that instead of one

amplifier for all the electrode assemblies, each electrode assembly includes an amplifier integral with the assembly as taught by Levendowski et al to effectively locally amplify the signals from each electrode assembly and thus reduce the amount of subsequent amplification required, thereby simplifying the device.

6. However, Finkenzeller et al in combination with Levendowski et al do not disclose a diagnostic analyzer operably configured to characterize the amplified AER signal and to compare the characteristics to at least one predetermined AER characteristic, wherein the at least one predetermined AER characteristic is associated with a neurological condition. John et al disclose an analogous device comprising a diagnostic analyzer 242 configured to characterize the AER signal and to compare the characteristics to at least one predetermined AER characteristic in master database 250, wherein the at least one predetermined AER characteristic is associated with a neurological condition, best seen in Figure 12-13 (¶0315). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a diagnostic analyzer with the device of Finkenzeller et al as modified by Levendowski et al to characterize the AER signal and to compare the characteristics to at least one predetermined AER characteristic, as taught by John et al, to effectively determine the presence of a neurological condition.

7. **Claim 2**: Finkenzeller et al disclose a cantilevered flexible arm 12 connecting the signal electrode 21 to the frame 10, best seen in Figure 1.

8. **Claim 3**: Finkenzeller et al disclose a second signal electrode 21 attached to the frame, best seen in Figure 2.

9. In regards to **Claim 7**, Finkenzeller et al in combination with John et al disclose the invention above as claimed including teaching that the complete device may be mounted on the frame (Col.4: 65-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have a flexible printed circuit harness containing the electrodes and communication paths to the AER data processor which is well known to one skilled in the art as an effective circuit and electrode structure to effectively have all components of the device mounted onto the frame and shaped for conforming to the head under the resilient urging of the frame.

10. **Claim 11**: Finkenzeller et al in combination with John et al disclose the at least one predetermined AER characteristic is capable of comprising a dyslexic AER characteristic.

11. **Claim 13**: Finkenzeller et al disclose the AER data processor 1 comprises a control module integral to the frame (Col.4: 65-67).

12. **Claim 14**: Finkenzeller et al disclose the frame 10 includes a disposable portion that includes the electrodes 21, 22.

13. **Claim 15**: Finkenzeller et al disclose the AER data processor 1 necessarily includes digital storage configured to store the AER data.

14. **Claim 16**: Finkenzeller et al disclose the AER data processor 1 is necessarily operably configured to perform a sequence of screening tests, and to store in the digital storage AER data associated with each test.

15. **Claim 17**: Finkenzeller et al disclose the digital storage further includes a predetermined test protocol.

16. **Claim 18**: Finkenzeller et al disclose the AER data processor 1 is further operably configured to generate a user indication of a test condition.

17. **Claim 19**: Finkenzeller et al disclose the frame 10 is operably shaped to connect between the ears across a front portion of a patient's head, best seen in Figure 1-2.

18. In regards to **Claim 20**, Finkenzeller et al in combination with John et al disclose the invention above as claimed but do not disclose a pair of ear cups attached to each end of the frame. However, Finkenzeller et al teach that the device can be advantageously used for both the left and right ears by rotating the device to position ear cup 30 accordingly (Col.3: 44-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have a pair of ear cups attached to each end of the frame to effectively enable use of both the left and right ears without having to reposition the device.

19. **Claim 21**: Finkenzeller et al disclose the frame 10 comprises an ear cup 30 having a resilient portion inwardly affixed thereto, best seen in Figure 1-2.

20. **Claim 22**: Finkenzeller et al disclose the frame 10 further comprises an ear cup 30 having an electrode 21 registered caudad to the sylvan fissure of a subject, best seen in Figure 1-2.

21. **Claims 23-25 and 28** are rejected under 35 U.S.C. 103(a) as being unpatentable over Finkenzeller et al (US Pat No. 5954667) in view of John et al (US Pub No. 20010049480), further in view of John (US Pub No. 20050018858), and even further in view of Clauson et al (US Pat No. 5423327).

22. In regards to **Claims 23 and 28**, Finkenzeller et al disclose a method of performing auditory evoked response (AER) testing, comprising: positioning a device, best seen in Figure 1-2 on the head of a subject, the device positioning a sound producer 30, a reference electrode 22 and a signal electrode 21; generating an auditory stimulus with the sound producer; and recording AER data across the reference and signal electrodes with signal generator/evaluation unit 1, wherein the act of recording AER data comprises receiving electrode voltage data as sensed by the reference electrode and signal electrode (Col.3: 59-65).

23. However, Finkenzeller et al do not disclose a data analyzer operably configured to characterize the AER signal and to compare the characteristics to at least one predetermined AER characteristic, wherein the at least one predetermined AER characteristic is associated with a neurological condition. John et al disclose an analogous device comprising a data analyzer 242 configured to characterize the AER signal and to compare the characteristics to at least one predetermined AER characteristic in master database 250, wherein the at least one predetermined AER characteristic is associated with a neurological condition, best seen in Figure 12-13 (¶0315). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a data analyzer with the device of Finkenzeller et al to characterize the AER signal and to compare the characteristics to at least one predetermined AER characteristic after connecting the device to the data analyzer, as taught by John et al, to effectively determine the presence of a neurological condition.

24. However, Finkenzeller et al in combination with John et al (2001) do not disclose detecting whether the sensed electrode voltage exceeds a threshold, wherein the act of

generating the auditory stimulus further comprises imposing a sampling delay in pursuit of a resting brain state in response to determining that the sensed electrode voltage exceeds a threshold. John et al (2005) teach that a sampling time delay is effective when sampling the AER signal to prevent undue noise or artifacts in the signal (¶0076). Clauson et al teach that detecting whether a signal exceeds a threshold, i.e. a pre-stimulus delay is shorter than the duration of an apnea condition, prior to application of a stimulus, to effectively prevent false readings such as from false positives or artifacts by employing a time delay to return the oxygen saturation level in the blood to normal (Col.3: 58-Col.4: 11). Clauson et al thus teach that it is critical to use a time delay to enable the measured levels to begin at normal before application of the stimulus. Clauson et al also teach that it is effective to wait for the measured physiological parameter (oxygen level) to return to a resting normal level before stimulation to ensure accuracy of measurement (Col.4: 1-11). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Finkenzeller et al in combination with John et al (2001) to include detecting whether the sensed electrode voltage exceeds a threshold, wherein the act of generating the auditory stimulus further comprises imposing a sampling delay in pursuit of a resting brain state in response to determining that the sensed electrode voltage exceeds a threshold, as well as detecting a resting brain wave and initiating the auditory stimulus at a predetermined parameter of the brain wave such as the slope of the resting brain wave, as taught by both John et al (2005) and Clauson et al above respectively, to effectively ensure that the sensed electrode voltage reading is accurate by imposing a sampling delay when the artifact level exceeds a threshold.

25. **Claim 24**: Finkenzeller et al in combination with John et al disclose recording the AER data further comprises necessarily storing the AER data on the device; transmitting the stored AER data to the data analyzer.

26. **Claim 25**: Finkenzeller et al disclose positioning the device on the head of the subject further comprising positioning the subject face up and positioning the device across a forward portion of the subject's head, best seen in Figure 1-2.

27. **Claims 4-6, 8-10, and 30-32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Finkenzeller et al in view of John et al (2001) and Levendowski et al; or Finkenzeller et al in view of John et al (2001), John et al (2005), and Clauson et al; further in view of Lencioni, Jr (US Pat No. 4219028).

28. In regard to **Claims 4-6 and 30-32**, Finkenzeller et al in combination with John et al (2001) and Levendowski et al, or Finkenzeller et al in combination of John et al (2001), John et al (2005), and Clauson et al, disclose the invention above as claimed but do not disclose the use of a multiplexing channel. Lencioni, Jr teaches that a multiplexing channel 18, 20 is effectively used to assign the electrodes of a device to enable proper sampling of the desired electrode in turn (Col.1: 21-22; Col.5: 21-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the invention of Finkenzeller et al as modified by John et al (2001) and Levendowski et al, or Finkenzeller et al as modified by John et al (2001), John et al (2005), and Clauson et al, to include a multiplexing channel as taught by Lencioni, Jr to effectively enable the AER data processor to selectively sample from the

first and second signal electrodes, wherein it is obvious that the electrodes can be sampled at any desired frequency such as sampling the first signal electrode at a low frequency sampling rate and sampling the second signal electrode at a high frequency.

29. In regard to **Claims 8-10**, Finkenzeller et al in combination with John et al (2001) and Levendowski et al, or Finkenzeller et al in combination of John et al (2001), John et al (2005), and Clauson et al, disclose the invention above as claimed but do not disclose associating a test subject identification with the AER signal. Lencioni, Jr teaches that a test subject identification is associated with a sampled electrode signal to effectively enable distinction of the test results for each individual test subject (abst). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Finkenzeller et al as modified by John et al (2001) and Levendowski et al, or Finkenzeller et al as modified by John et al (2001), John et al (2005), and Clauson et al, to have a test subject identification associated with the AER signal as taught by Lencioni, Jr, wherein it is well known to a skilled artisan that a test subject identification device may comprises known means such as a barcode scanner or a radio frequency identification scanner, to effectively enable distinction of the AER signal for different test subjects.

30. **Claims 12 and 29** are rejected under 35 U.S.C. 103(a) as being unpatentable over Finkenzeller et al in view of John et al (2001) and Levendowski et al; or Finkenzeller et al in view of John et al (2001), John et al (2005), and Clauson et al, further in view of Zoth et al (US Pat No. 6786873).

31. In regards to **Claim 12**, Finkenzeller et al in combination with John et al (2001) and Levendowski et al, or Finkenzeller et al in combination of John et al (2001), John et al (2005), and Clauson et al, disclose the invention above as claimed but do not disclose the diagnostic analyzer is coupled to the frame via a communication link. Zoth et al teach the advantages of a communication link to remotely access and transfer data between an analogous diagnostic analyzer and a remote location, best seen in Figure 1-4. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the diagnostic analyzer coupled to the frame of Finkenzeller et al as modified by John et al (2001) and Levendowski et al, or Finkenzeller et al as modified by John et al (2001), John et al (2005), and Clauson et al, via a communication link as taught by Zoth et al as an effective means to transfer data between the two.

32. In regards to **Claim 29**, Finkenzeller et al in combination with John et al (2001) and Levendowski et al, or Finkenzeller et al in combination of John et al (2001), John et al (2005), and Clauson et al, disclose the invention above as claimed but do not disclose accessing a remotely stored auditory testing protocol into the device. Zoth et al teach the advantages of a communication link to remotely access and transfer data between an analogous diagnostic analyzer and a remote location, best seen in Figure 1-4. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the invention of Finkenzeller et al as modified by John et al (2001) and Levendowski et al, or Finkenzeller et al as modified by John et al (2001), John et al (2005), and Clauson et al, access remotely stored data such as an auditory testing protocol

as taught by Zoth et al to effectively enable access of necessary data into the device for testing.

33. **Claim 33** is rejected under 35 U.S.C. 103(a) as being unpatentable over Finkenzeller et al in view of John et al (2001), further in view of John et al (2005), and even further in view of Seeley et al (US Pat No. 4132226).

34. Finkenzeller et al disclose a method of performing auditory evoked response (AER), comprising: positioning a device, best seen in Figure 1-2 on the head of a subject, the device positioning a sound producer 30, a reference electrode 22 and a signal electrode 21; generating an auditory stimulus in accordance with a predetermined epoch of auditory stimulus, the auditory stimulus being generated through the sound producer; sampling AER data wherein the sampling comprises recording AER data across the reference and signal electrodes with signal generator/evaluation unit 1(Col.3: 59-65).

35. However, Finkenzeller et al do not disclose a data analyzer operably configured to characterize the AER signal and to compare the characteristics to at least one predetermined AER characteristic, wherein the at least one predetermined AER characteristic is associated with a neurological condition. John et al disclose an analogous device comprising a data analyzer 242 configured to characterize the AER signal and to compare the characteristics to at least one predetermined AER characteristic in master database 250, wherein the at least one predetermined AER characteristic is associated with a neurological condition, best seen in Figure 12-13 (¶0315). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a data analyzer with the device of Finkenzeller et al to characterize the

AER signal and to compare the characteristics to at least one predetermined AER characteristic after connecting the device to the data analyzer, as taught by John et al, to effectively determine the presence of a neurological condition.

36. However, Finkenzeller et al in combination with John et al (2001) do not disclose monitoring the AER data for the presence of an artifact and in response to determining the AER data to contain an artifact, imposing a sampling delay and repeating an epoch of auditory stimulus and sampling AER data. John et al (2005) teach that a sampling time delay is effective when sampling the AER signal to prevent undue noise or artifacts in the signal (¶0076). Seeley et al disclose an analogous biopotential detection device wherein a sampling delay is imposed upon the detection of an artifact, and after the delay has been imposed, repeating the sampling to effectively ensure that the recorded are not erroneously affected by the artifacts (Col.4: 1-61). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Finkenzeller et al as modified by John et al (2001) such that the AER data is monitored for the presence of an artifact and in response to determining the AER data to contain an artifact, imposing a sampling delay and then repeating an epoch of auditory stimulus and sampling AER data as taught and suggested by John et al (2001) and Seeley et al, to effectively lessen the effects of noise or artifacts into the epochs of sampled AER data.

Response to Arguments

37. Applicant's arguments with respect to the above claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HUONG NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736